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09/253,153 02/19/99 SCHWABACHER

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EXAMINER

GARCIA, M

ART UNIT

PAPER NUMBER

1627

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/253,153

Applicant(s)
Schwabacher

Examiner
Maurie E. Garcia, Ph. D.

Group Art Unit
1627



☒ Responsive to communication(s) filed on Oct 23, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-46 is/are pending in the application

Of the above, claim(s) 8-36 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7 and 37-46 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The Response filed October 23, 2000 (Paper No. 9) is acknowledged. Claims 1 and 7 were amended, no claims were cancelled and claims 37-46 were added. Therefore, claims 1-46 are pending.

2. This application contains claims 8-36 that have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions. Election was made without traverse in Paper No. 5. Newly added claims 37-46 fall within the elected group.

Specification-Sequence Listing

3. The examiner acknowledges the corrected submission of the sequence listing filed October 25, 2000. The application now complies with the requirements of 37 CFR 1.821 through 1.825.

Withdrawn Rejections

4. The rejection of claims 1 and 7 are under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicant's amendments. The rejection of claims 1, 2, 5 and 6 under 35 U.S.C. 102(b) as being anticipated by Fodor et al is also withdrawn in view of applicant's amendments.

Maintained Rejections
Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-7 and newly added claims 37 and 38 are rejected under 35

U.S.C. 102(b) as being anticipated by Lebl et al (EP 0 385 443 A2: listed on PTO-1449, Paper No. 2).

Lebl et al discloses a method for synthesizing oligomers on a solid support that is in the form of a band, thus forming “an array of chemical compounds” (see Abstract and Fig. 1, reference numeral 1 of the patent). The band carrier of Lebl et al is “led, e.g. by means of a series of rollers, through the appropriate reagents and washing solvents so that individual reactants are step-wise bonded” (see page 4, lines 30-34). Furthermore, in the process of Lebl the steps proceed at locally different sites (see page 4 lines 35-38). The arrays of Lebl et al are subjected to reaction conditions such as coupling of amino acids (for example) by deprotection and activation. These steps “cycle” along the support as a function of a unique distance and time (defined by the cycle through the system – see Figure 1 and page 5, lines 12-29) and clearly involve more than one reagent. See, for example, Example 10 of Lebl et al on page 9. Also, conventional protecting groups for peptide chemistry are used in the syntheses (see, for example, page 4, lines 39-

46). The carriers can be those such as thread (see claims 1 and 5 of Lebl et al) which are "one-dimensional".

Additionally, the examiner respectfully points out that claims 2-4 and 6 are product-by-process claims and that any "array of chemical compounds" reads on such claims. The process by which the claimed array is synthesized does not appear to lend patentable weight to the claimed invention. One of ordinary skill would expect the array to be the same regardless of the manner of synthesis.

Response to Arguments

7. Applicant's arguments filed October 23, 2000 have been fully considered but are not found persuasive. The arguments are addressed in detail below.

8. Applicant argues that Lebl et al do not teach "at least two chemical compounds linearly arranged on a support". However, as stated above, in the process of Lebl the coupling steps for amino acids proceed at locally different sites (see page 4 lines 35-38). These steps "cycle" along the support as a function of a unique distance and time (defined by the cycle through the system). The entire support can be taken all the way to end product, or *stopped at an stage having a series of intermediate compounds present on the support* (see patented claim 8). Since Lebl et al teach a compound containing two Gly moieties (see page 7, lines 1-20 of the reference), the reference reads on a support having one compound present at two different positions.

New Rejections – Necessitated by Amendment
Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 43-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for amino acids/peptides, does not reasonably provide enablement for any “synthesis products”. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is clear from applicant’s specification how one might practice this invention with amino acids/peptides; however, there is insufficient guidance as to how to make/use any “synthesis products”. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include, but are not limited to:

- (1) the breadth of the claims;
- (2) the nature of the invention;
- (3) the state of the prior art;
- (4) the level of one of ordinary skill;
- (5) the level of predictability in the art;
- (6) the amount of direction provided by the inventor;
- (7) the existence of working examples; and
- (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claims and the nature of the invention: The claims simply recite that “synthesis products” are attached to the support. No other limitations on the “synthesis products” are given and, as such, this could read on a wide variety of structures. Such represents very broad scope. The state of the prior art and the level of predictability in the art: Arrays of amino acids/peptides were known at the time of filing; however, only limited numbers of arrays of all other compounds were known. However, it was known that synthesis of compounds on solid supports is unpredictable in the absence of a specific protocol. The instant specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of *any* “synthesis products”. The structures of possible variants are sufficiently diverse and one of ordinary skill would not be able to predict their structures and linkage chemistry. The level of one of ordinary skill: The level of skill would be high, most likely at the Ph.D. level. The existence of working examples: Applicants have only provided examples of amino acids/peptides; therefore further research would be necessary to make or use the invention for *any* other type of chemical compound (i.e. synthesis product) since one of ordinary skill could not guess, *a priori*, how to make and use any such a compound. The quantity of experimentation needed to make or use the invention based on the content of the disclosure: In claims 43-46 there is only the broad recitation that “synthesis products” are attached to the support. However, the instant specification gives one skilled in the art no indication that one could use *any*

compound and have a reasonable expectation of success. Further research would be necessary to make or use the invention for *any* type of compound. Therefore, the practice of the full scope of the invention would require undue experimentation.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 43-46 recite "synthesis product" and define them as including a "plurality of distinct chemical structures" or "single chemical structures". This is extremely confusing since it is unclear what constitutes a "synthesis product" (is a single amino acid linked to a support a synthesis product?) and how what appears to be a single synthesis product can include a plurality of distinct structures. Clarification is requested.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 38-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebl et al (EP 0 385 443 A2: listed on PTO-1449, Paper No. 2) in view of Lebl et al (US 5,688,696: listed on PTO-1449, Paper No. 2).

The teachings of Lebl et al (EP 0 385 443 A2) are set forth supra. The reference teaches a method for synthesizing oligomers on a solid support that is in the form of a band, thus forming "an array of chemical compounds". The reference lacks the teaching of duplicate compounds in different positions as set forth in the instant claims 38-42.

However, it was well known in the art at the time of the invention to make duplicate arrays of compounds. For example, Lebl (US 5,688,696) teach making arrays of compounds on a similar, one-dimensional carrier (thread; see column 7, lines 30-67). Lebl (US 5,688,696) makes these arrays in duplicate (see column 8, lines 9-42) so that a control can be used in the screening of the library.

Therefore, it would have been prima facie obvious to make the one dimensional array of chemical compounds as taught by Lebl et al (EP 0 385 443 A2) using any number of duplicate compounds. Lebl (US 5,688,696) teach that duplicate compounds in combinatorial chemistry arrays are advantageous in the screening process. Thus, one would have been motivated to use duplicates in the

array of by Lebl et al (EP 0 385 443 A2) as taught by Lebl (US 5,688,696) to assist in screening of the compounds of the array.

Status of Claims/Conclusion


15. No claims are allowed.
16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.
17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703)

308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.
January 15, 2001


DR. JYOTHSNA VENKAT PH.D.
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